

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

USSN 10/032,372

Atty. Dkt. A-035 US

REMARKS

Claims 1-23 and 38-45 are pending in the application. Claims 12, 41 and 43 stand withdrawn from consideration as being drawn to a non-elected species as a result of an earlier election requirement. Claims 24-37 and 46-50 have been cancelled as a result of an earlier restriction requirement. Pursuant to the January 16, 2004 Office Action, Claims 1-22, 13-23, 38-40, 42, 44 and 45 stand rejected.

By the foregoing amendment, Claim 38 has been further amended to remove the relation back to Claim 1 and insert the description of the antimicrobial microcapsules. New dependent Claims 51-54 have been added to provide further iterations of the particle sizes for the antimicrobial microcapsules of the independent claims from which they depend; new dependent Claims 55 and 56 provide further iterations of the types of antimicrobial agents that may be incorporated into the polymer compositions; and new dependent Claims 57 and 58 set forth the two iterations of the microcapsules. No new matter has been entered as support for these newly added claims is found at page 14, lines 2-5; in Claims 4 and 5 and in Claims 22 and 23, respectively.

Claim Rejections:

Claims 1-11, 13-23, 38-40, 42, 44 and 45 stand rejected under 35 USC §103(a) as being unpatentable over Hagiwara et. al. (US 4,775,585) in view of Konagaya et. al. (US 6,013,275), Niira et al. (US 5,556,699) and Wada et. al. (US 3,981,970). The cited art is said to teach the following: 1) Hagiwara et al. teach the incorporation of antibacterial zeolite particles in polymers such as ABS; 2) Konagaya et al. teach that the antibacterial activity of silver zeolite can be increased by incorporating the same in a hydrophilic substance and that the same can be further incorporated into a suitable thermoplastic or thermosetting resin; 3) Niira et al. teach silver zeolites further incorporating ammonium ions for the prevention of discoloration of resins into which they are incorporated and 4) Wada et al. teach ion-exchange mechanisms involving zeolites, especially silver zeolites, including an exchange process whereby nitric acid is introduced to silver zeolite with the result being hydrogen zeolite, silver nitrate and excess nitric acid. Reiterating its prior rejection, the Patent Office states that while the art does not specifically disclose a silver zeolite encapsulated with an acrylic resin, especially (hydroxyethyl methacrylate), having an average diameter of about 2000 microns or less, optionally further

/pat/microencap/1.16.04 response

USSN 10/032,372

Atty. Dkt. A-035 US

comprising an ammonium salt or sodium nitrate or optionally further incorporated into an addition polymer, especially ABS, the art amply suggests combining silver zeolites with hydrophilic polymers, such as acrylics, and with other polymers, such as ABS, as well as the use of ammonium ions and the exchange of silver with sodium ions and nitric acid. As such, the Patent Office alleges that it would have been well within the skill of the art and one skilled in the art would have been motivated to modify the prior art so as to arrive at Applicants' compositions with the expectation that antibacterial activity would be enhanced, that the ammonium ions would inhibit discoloration of polymer resins such as ABS and that the addition of sodium nitrate would drive the release of silver ions, thereby increasing the amount of silver ions available for antibacterial activity. In conclusion, it is alleged that the claimed invention as a whole would have been *prima facie* obvious to one skilled in the art at the time the invention was made because each element of the invention has been collectively taught by the combined teachings.

The Patent Office states that Applicants' prior response was not persuasive as Applicants cannot show non-obviousness by attacking references individually where the rejection is based upon a combination of references and, further that the test is not whether the features of the secondary reference may be bodily incorporated into the structure of the primary reference, nor that the invention be expressly suggested in any one or all of the references; rather the test is what the combined teaching of the references would have suggested to those of ordinary skill in the art. In addressing Applicants' argument of criticality of the particle size, the Patent Office states that Applicants have not provided any evidence of criticality and that arguments of counsel are not sufficient and, in any event, Hagiwara shows the claimed particle sizes. In addressing Applicants' arguments that the references do not show the encapsulation of the antimicrobial agent, the Patent Office merely states that Konagaya shows the incorporation of its antimicrobial agent into suitable thermoplastic or thermosetting resins. Finally, in addressing Applicants' arguments as to Wada, the Patent Office reiterates that counsel's arguments are not sufficient and, in any event, the Patent Office contends that the prior art teaches (a) that the exchange of ions is an equilibrium reaction, (b) that the addition of sodium ions will result in the replacement of silver ions, and (c) that nitric acid will result in the exchange of silver and, consequently, one would expect sodium nitrate to result in the exchange of silver ions as well

/pat/microencap/1.16.04 response

USSN 10/032,372

Atty. Dkt. A-035 US

from the zeolite. In summary, the Patent Office states that the invention as a whole is *prima facie* obvious since all of the elements have been collectively taught by the combined teachings of the references.

Applicants respectfully traverse the Patent Office's positions as a whole as well as individually. The Patent Office has failed to appreciate Applicants' invention, has failed to consider the whole of the teachings and limitations of the cited references and has misapplied the relied upon case law in this instance.

The Patent Office's recitation of certain passages of *In re Keller*, while correct, is not a complete recitation of the test for obviousness. While a statement that one cannot consume coffee is an accurate statement relative to a doctor's order that the individual not consume caffeine, it is not the whole story. Similarly, Applicants' acknowledge that attacking the individual references is not, in and of itself, sufficient to overcome a rejection; however, each reference must be assessed on its own merit to ascertain its teachings, its applicability to the technology of the claimed invention, etc. And, while the Patent Office is correct that the claimed invention need not be expressly suggested, there is still an absolute requirement that there be some motivation, suggestion or incentive supporting the modification of the primary reference by the secondary reference to arrive at the claimed invention. (See e.g., *In re Geiger*, 2 PQ2d 1276 (CAFC 1985)). The mere fact that the references can be combined does not render the resultant combination obvious. In assessing the appropriateness of the combination being expounded, one has to consider all of what the references teach as well as the general knowledge of the art, and may not ignore the non-analogous nature of the art, if appropriate, or the express teachings of the art, regardless of whether such teachings are consistent with or teach away from the claimed invention.

Though the Patent Office recites the rejection as being based on Hagiwara in view of Konagaya, Niira and Wada, it is not explicit whether the rejection is based on a combination of all four references as applied to each claim or whether there are different combinations of references to be applied to specific claims. Absent such explicitness, it seems that Hagiwara and Konagaya constitutes the key basis for rejection of the independent claims and the majority of dependent claims while the further combination with Niira applies to those claims where ammonium ions are present and the further combination with Wada applies to the presence of

/pat/microencap/1.16.04 response

USSN 10/032,372

Atty. Dkt. A-035 US

the sodium nitrate. Based on the arguments presented by the Patent Office, this would seem the most logical reading and will be the basis for this response.

Hagiwara in view of Konagaya

As noted in the attached Declaration of Jeffrey A. Trogolo, a co-inventor of the present invention, (the "Declaration"), while many of the materials used in or identified as useful in the combined teachings of Konagaya and Hagiwara, as well as the former alone, are the same as or similar to those used in the present invention, both of these references, individually and in combination, fail to teach the specific selection and combination of materials so as to arrive at the two phase system of Applicants' invention. As noted in the Declaration and by the Patent Office, Konagaya refers to the need to select a "suitable" thermoplastic or thermosetting resin. This clearly indicates that there are limitations on the selection of such materials. Konagaya provides little guidance as to "suitability", as noted further below, and, thus, one must look to the knowledge or skill of persons of ordinary skill in the art. As set forth in the Declaration, "suitability", particularly with respect to polymer compositions and, especially for those to be used in the preparation of films and the like, is typically understood by those skilled in the art to require compatibility amongst the polymer constituents to be combined. Such compatibility is most readily evident by a single phase composition, not a two phase system as required by the present invention. Looking to Konagaya, the only hints or guidance provided with respect to what is or is not "suitable" is found in the examples, particularly Examples 42-44, where Konagaya employs materials that those skilled in the art would recognize as being miscible in, thus, compatible with, one another or, in the case of the specified examples, where Konagaya expressly infers that a transesterification and/or chain scission occurs so as to create a new copolymer (See Col. 28, lines 63-67).

Stated in the most simplest of terms, the combined teachings of Konagaya and Hagiwara provide hydrophilic copolymers and/or alloys having dispersed therein the antimicrobial agent; whereas, Applicants provide a two-phase system having a non-hydrophilic (or hydrophilic polymer of a different hydrophilicity) matrix in which is dispersed discrete domains of hydrophilic polymer having dispersed or encapsulated therein the inorganic antimicrobial agent. In the former, the antimicrobial agent dispersed throughout the bulk of the polymer is able to be transported through the polymer and, thus, is available or accessible to provide antimicrobial

/pat/microcomp/1.16.04 response

USSN 10/032,372

Atty. Dkt. A-035 US

properties. On the other hand, the discrete domains or microparticles according to the present invention serve as reservoirs of the antimicrobial agent wherein only those reservoirs at or near the surface of the polymer matrix are available to provide antimicrobial properties. Those domains or microparticles within the polymer are inaccessible and do not contribute to the antimicrobial properties until such time as they become exposed. In this latter respect, further contrasting the present invention from the combined teachings is that while the antimicrobial agent throughout the bulk of the reference materials will be depleted over time, only that antimicrobial agent in the domains at or near the surface will be depleted in Applicants invention. Thus, those domains below the surface will be able to serve as future reservoirs of the antimicrobial agent as the matrix polymer wears away in use, thus exposing new, fully charged domains whose antimicrobial agent is now accessible.

Another aspect which distinguishes and further differentiates the claimed compositions from the combined teachings is with respect to the physical properties and characteristics of the resultant polymer compositions of each. As noted in the Declaration, those skilled in the art recognize that the creation of copolymers as well as alloys of miscible or compatible polymers results in a polymer composition whose physical properties and characteristics are different from those of the individual polymers (in the case of blends or alloys) or from the respective homopolymers that would be attainable from the different mers (in the case of copolymers). Most often these compositions will reflect some, though not all, and to a lesser extent, the properties of the starting materials or related homopolymers. This is even acknowledged by Konagaya where, for example, Konagaya teaches that using in excess of 20% polyethylene glycol adversely affects the physical properties of the antibacterial composition (See Konagaya, Col. 11, lines 54-64). The foregoing is in conflict with and contrasts with a key objective of the present invention which is to minimize, if not eliminate, any potential adverse consequence on the physical properties and attributes of the matrix polymer by preserving the chemistry of the matrix polymer as best possible. This is accomplished by achieving a two phase system and limiting the particle size of the dispersed phase.

As noted above, the Patent Office states that the arguments of counsel relative to the criticality of the particle size is not sufficient and, in any event, that Hagiwara teaches the claimed particle size. While the Patent Office is correct in that Table I of Hagiwara speaks of

/pat/microencap/1.16.04 response

USSN 10/032,372

Atty. Dkt. A-035 US

particle sizes, it does so with respect to the inorganic antimicrobial agent, not of an encapsulated antimicrobial agent. Indeed, the particle sizes of the inorganic antimicrobial agent of Hagiwara are consistent with the particle sizes of the antimicrobial agents employed in making the antimicrobial hydrophilic polymer microcapsules of the claimed invention (see page 11, line 25 through page 12, line 3). Thus, Hagiwara appears irrelevant to the present rejection.

Applicants acknowledge the Patent Office's remark concerning the use of the term "about" in relation to the average particle size but traverse the same. The qualifier "about" is commonly used in claims in recognition of the fact that precise demarcation is neither appropriate nor oftentimes able to be identified at the time of filing. As is well established in patent law, one looks to the goals and objectives of the claimed invention to appreciate the metes and bounds of the limitations set forth therein where not stated with exact precision. Applicants believe that those skilled in the art would appreciate and understand the scope of the claims as now written, particularly in light of the arguments set forth below and in the specification relative to concerns on particle size.

Furthermore, since neither Hagiwara nor Konagaya nor their combined teachings suggest or motivate one to form an encapsulated inorganic antimicrobial agent, either as individually coated particles of the antimicrobial agent or as microcapsules containing multiple particles of the antimicrobial agent dispersed in a hydrophilic polymer, the issue of particle size is moot. If you are not motivated to make the particles, there is no relevance to their size. Yet, as set forth in the Declaration, the particle size of the encapsulated antimicrobial agents and microcapsules of the present invention is critical and impacts directly the performance of the compositions into which they are to be incorporated. Indeed, at page 13, lines 27-31, and page 14, lines 7-10 of the specification, Applicants warn against employing too thick of an encapsulant layer where individual particles are to be encapsulated as well as against too large of particles in the case of the microcapsules, respectively, so as to avoid or minimize any impact they may have on the physical properties and characteristics of the matrix resin into which they are to be incorporated.

In light of the foregoing and the further arguments and statements of Jeffrey A. Trogolo and in view of the clear claim language of the polymer composition claims which require a two-phase system, any presumption of *prima facie* obviousness has been rebutted and the rejection should be withdrawn and the application passed on to allowance.

/pat/microencap/1.16.04 response

USSN 10/032,372

Atty. Dkt. A-035 US

Hagiwara in view of Konagaya and Niira

The further reliance upon Niira does not add to the alleged strength of the Patent Office's rejection of the independent claims as Niira teaches much the same as Hagiwara with the exception that its polymer compositions are formed into films. There is nothing to suggest, infer or motivate one to create encapsulated antimicrobial agents, either as individual particles or as microcapsules, and to employ those microcapsules as a distinct phase in a polymer composition. Indeed, as further discussed in the Declaration, a two phase system is not generally suitable for forming polymer films. Such inappropriateness or non-suitability is even more evident from Niira itself where it specifies that the film thickness be more than 15 microns; yet the particle sizes of the antimicrobial agents of the present invention are generally much greater than 15 microns.

The Patent Office appears to predominately rely upon Niira as demonstrating the use of ammonium ions in the antimicrobial agent; however, Applicants do not contest that the inclusion of such ions in the antimicrobial zeolite would provide protection against discoloration. However, what is unique in Applicants' composition is that the ammonium ions will tend to react with those color forming constituents in the hydrophilic encapsulant layer or material and not in the matrix polymer, thereby further reducing the likelihood of discoloration of the latter. Thus, as a further benefit of the present invention, those reactions which oftentimes cause discoloration or which help prevent discoloration, as with the use of the ammonium ions, are now essentially restricted to the hydrophilic material and do not, at least not to any significant extent, extend into the polymer matrix (See page 7, line 29 through page 8, line 2). This benefit is not at all inherent from, suggested in or inferred by the references, alone or in combination.

Hagiwara in view of Konagaya and Wada

Applicants do not argue with the Patent Office's remarks that the prior art teaches the ion exchange as an equilibrium reaction, that sodium ions will exchange with silver ions or that nitric acid will also exchange with silver; however, Applicants traverse the conclusion of the Patent Office that, in light of the foregoing, one skilled in the art would expect sodium nitrate to then result in the exchange of silver. This is an instance where the Patent Office accurately recites certain elements of the reference but not all and those that it does are taken out of context.

/pat/microencap/1.16.04 response

USSN 10/032,372

Atty. Dkt. A-035 US

As noted in Applicants' prior response, Wada teaches a two step process for the recovery of silver from a solution which method uses a sodium zeolite to take up the silver ions, it then isolates the silver zeolite and finally reacts that with nitric acid to release and bind the silver ion to the nitrate ion. Nitric acid does not exchange, rather it is the hydrogen proton that exchanges so as to release the silver ion which is then captured and bound by the nitrate ion, thereby forming silver nitrate, a colorant. Furthermore, unlike the compositions of the present invention where many different chemical constituents are present, the systems of Wada are controlled to include only those materials that are needed to effectuate the desired reaction. Indeed, the sodium is removed before the nitric acid is introduced. Applicants are at a loss to understand how the Patent Office reconstructs Wada to allow the use of sodium nitrate when Wada does not employ or teach the use of such a material and, though it does teach the presence of each ion making up sodium nitrate, it teaches the sequential use of each in the absence of the other.

In addressing Applicants' prior response, the Patent Office stated that arguments of counsel are not appropriate. However, it is not the arguments of counsel but the teachings of Wada that are being set forth. With the prospect of the formation of silver nitrate, those skilled in the art would likely avoid such a circumstance since discoloration is already an issue. Besides coloration, those skilled in the art would also have concern with respect to the binding of the silver which would suggest that the silver ion is not available to act in antimicrobial manner.

Perhaps the most telling sign of the inappropriateness of Wada as a reference is the fact that Wada creates a new zeolite, Zeolite OTW, in order to effectuate its process. Such a zeolite is critical since, as noted at Column 1, lines 49-54, Wada teaches that the use of an acid to elute a metal cation cannot be accomplished in a typical zeolite, especially zeolite type A, since they are decomposed in the acid. Thus, the rejection based upon the combined teachings of Hagiwara in view of Konagaya and Wada is without merit and should be withdrawn.

Conclusion

Contrary to the assertions of the Patent Office, none of the cited art, alone or in combination, speak of, suggest, infer or motivate one to produce the particulate, encapsulated antimicrobial agents of the present invention and employ them in polymer compositions as a discrete second phase for enhanced antimicrobial efficacy and control. Consequently,

USSN 10/032,372

Atty. Dkt. A-035 US

applicants respectfully request that the rejections be withdrawn and the application, as amended above, be passed on to allowance.

Petition For Extension of Time

By this response, Applicants hereby petition for a three-month extension of time; thereby extending the response period from July 23, 2003 to and including October 23, 2003. Enclosed is payment of the Petition Fee in the amount of \$475.00.

Claims Fees

No addition fees are necessary as the total number of claims remaining after this amendment (36) does not exceed the highest number of claims previously paid for (50).

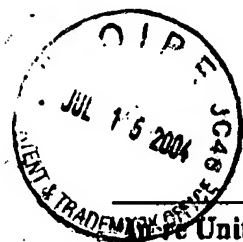
Applicants believe all matters raised in the Office Action have been fully addressed. Should there be any questions, please contact the undersigned, Applicant's attorney.

Respectfully submitted,



Edward K. Welch II
Attorney for Applicants
Registration No. 30,899
AgION Technologies Inc.
60 Audubon Road
Wakefield, MA 01880
Tel.: 781-718-9512*
Fax: 781-246-3314
e-mail: welched@comcast.net*

* new telephone number and e-mail address

**A-035 US
PATENT APPLICATION****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE****United States Patent Application of:****Applicant: Trogolo et al.****Serial No.: 10/032,372****Filed: December 21, 2001****Title: Encapsulated Inorganic Antimicrobial
Additive for Controlled Release****Examiner: F. I. Choi****Art Group: 1616****DECLARATION OF JEFFREY A. TROGOLO****PURSUANT TO 37 CFR 1.132**

I, Jeffrey A. Trogolo, hereby declare as follows:

I am Chief Technology Officer for AgION Technologies, Inc. and have held this position, in AgION Technologies, Inc. and its predecessor entities, since February of 1998.

I hold a Ph.D. in Materials Science and a B.S. in Materials Engineering from Rensselaer Polytechnic Institute in Troy, NY. I have published more than 10 papers in various journals including the Journal of Materials Science, the Proceedings of the Society for Biomaterials and the Proceedings of the Materials Research Society.

I have more than eight years experience in the field of antimicrobial modification of polymers and continue to have a hands-on research role investigating the capabilities and mode of activity of antimicrobial agents, especially the AgION silver zeolite antimicrobial agent, in various polymer compositions and coatings.

I am a co-inventor of the invention disclosed in and embraced by the claims of the above-referenced pending US patent application. I am aware of the arguments being set forth in rejecting this application, including the supposed lack of evidence supporting the criticality of the particle size.

I have read and given considerable thought to the teachings of the primary reference to Konagaya et. al. (US 6,013,275), hereinafter "Konagaya", and have concluded as follows:

Konagaya appears to deal with two disparate concepts. The first relates to antimicrobial compositions which are prepared by alloying or, preferably, grafting or copolymerizing a hydrophilic substance with an organic antimicrobial agent. Indeed, it is to this concept that

A-035 US
PATENT APPLICATION

Konagaya dedicates the greatest portion of its specification and examples. The second concept of Konagaya involves the preparation of antimicrobial compositions having an inorganic antimicrobial agent dispersed in a hydrophilic polymer or a polymer alloy wherein one of the components is a hydrophilic polymer. However, Konagaya provides very little teaching or direction in this regard and only a handful of examples reflect this embodiment (examples 36 to 44). It is this latter teaching which is being applied against our invention.

Though many of the materials identified as useful in Konagaya are similar to, if not the same as, those used in our invention and while both Konagaya and we have the same objective, enhancing antimicrobial activity without markedly increasing the amount of antimicrobial agent to be used, each of us uses those materials in different ways to achieve a similar, but very different result.

In its most basic iteration, Konagaya teaches and demonstrates that antimicrobial efficacy is enhanced when an inorganic antimicrobial agent is incorporated into a hydrophilic polymer as opposed to a non-hydrophilic polymer, especially where the former merely incorporates hydrophilic mers not found in the latter (See examples 36-41). Indeed, it is this concept that we have built upon to arrive at our invention. Specifically, though not described in Konagaya, we found that the water absorption characteristics of the hydrophilic polymer facilitates the transport of the antimicrobial metal ions through the polymer: thus, making all of the antimicrobial agent incorporated into that hydrophilic polymer accessible. This contrasts with non-hydrophilic polymers wherein essentially only that amount of antimicrobial agent present at the surface of the polymer is accessible since there is no transport mechanism to enable the passage of the antimicrobial metal ions from within the polymer to the surface.

While the antimicrobial hydrophilic compositions of Konagaya could be used to make the antimicrobial micro-particles of our invention, Konagaya does not teach, suggest or motivate one to do so. Even if one thought to do so, there would no reason or benefit in going through such additional effort or expense, at least not as far as Konagaya would be concerned. As noted, Konagaya prepares bulk polymer compositions which are molded or extruded as a polymer melt to form articles or stock materials or dissolved in solution for casting films or preparing coatings; adjusting particle size is not relevant. Instead, as is typical for formulated polymer compositions generally, Konagaya's antimicrobial compositions would most likely be palletized for transport and further processing. Such pellets typically have diameters of in excess of 2 mm and lengths of 4 mm or more. On the other hand, small particle size is critical to our invention, as will become clearer below.

Konagaya also teaches that its antimicrobial hydrophilic compositions can "be mixed with a suitable thermoplastic or thermosetting resin before the molding operation." Konagaya goes on to list a number of exemplary polymers, but provides no further direction or teaching in this regard, other than as set forth in Examples 42-44. However, the key point here is the requirement of suitability of the thermoset or thermoplastic with the hydrophilic material. I, and those skilled in the art, understand this term to mean that the thermoplastic or thermoset must be compatible with the antimicrobial composition, i.e., wholly or substantially miscible with the hydrophilic polymer so that a single phase polymer compositions results. This conclusion is consistent with Konagaya's intended end-use applications, particularly with respect to shrinkable and/or stretchable polymer films where such compatibility/miscibility is critical.

**A-035 US
PATENT APPLICATION**

Notwithstanding the foregoing, Konagaya's use of the term "suitable" may have an even narrower interpretation. Specifically, as shown in Examples 42-44, melt blending the hydrophilic polymer with a "suitable" thermoplastic produces a hydrophilic copolymer. Though not explained, it is believed that the copolymer results from transesterification and/or chain scission. Thus, it may well be that Konagaya intends that the selection of a "suitable" polymer is contingent upon its being capable of undergoing such a process with the hydrophilic polymer.

Regardless of which interpretation is correct, it is clear that a critical aspect of Konagaya's teaching is that the resultant polymer composition must, itself, be hydrophilic. Whether a copolymer, as exemplified, or an alloy, as I suggest, the resultant polymer composition is hydrophilic. Of course, the degree of hydrophilicity is less than that of the starting hydrophilic material. More importantly, the physical properties and characteristics of the resultant polymer will be different than either of the starting polymers themselves. The nature and extent of the change will depend upon the amount of non-hydrophilic material employed. While all of the antimicrobial agent in the resultant composition will still be accessible, the release rate will be lessened (versus the pure hydrophilic polymer) due to the lower hydrophilicity.

The foregoing differs markedly from the compositions made in accordance with our invention. Specifically, the encapsulated antimicrobial micro-particles of our invention, when incorporated into another polymer (the matrix polymer), remain as a discrete phase. They do not alloy or copolymerize. Consequently, the properties of the matrix resin remain essentially unchanged. Indeed, as set forth in our patent application, a key objective of our invention is to enhance antimicrobial efficacy without materially impacting the physical properties of the matrix polymer. In essence, any impact on the physical characteristics and attributes of the matrix polymer is minimized so that the matrix polymer continues to exhibit those properties and characteristics for which it was selected. While the composition as a whole exhibits some hydrophilicity, that hydrophilicity is solely attributable to the hydrophilic particles at the surface of the polymer matrix. Particles encased within the polymer matrix do not contribute as no water can reach them.

Particle size is critical for several reasons. First, for a given amount of the microencapsulated antimicrobial agent, the smaller the particle size, the greater the number of particles and the greater likelihood that any given particle will be at the surface of the matrix polymer into which it is incorporated. As noted above, if it isn't at the surface or very near the surface, it does not contribute to the antimicrobial efficacy. Secondly, the smaller the particle size, the less likely there is for any potential impact on the physical properties of the matrix resin. As known to those skilled in the art, large domains of an incompatible material can markedly affect the physical properties and characteristics of the matrix resin: admittedly both positively and negatively depending upon what one is trying to achieve. Thirdly, following on the first attribute, a greater number of particles also means there is less distance between particles at the surface, thus, ensuring better antimicrobial efficacy across the whole surface area. The greater the distance between particles, the greater surface area one particle has to serve and the greater the distance the antimicrobial ions have to traverse in order to provide uniform surface coverage.

Besides maintaining the physical properties of the matrix resins, the compositions of our invention will have several advantages over those of Konagaya. First, because our particles are concentrated

A-035 US
PATENT APPLICATION

reservoirs of the inorganic antimicrobial agent, we achieve a greater release of antimicrobial agent in a shorter period of time. In Konagaya, the ions within the bulk will have to travel further to get to the surface. Secondly, our materials are especially suited for those applications subject to surface wear. In this regard, the efficacious life of our material will be much greater since those particles which are entombed in the polymer matrix and unavailable, become available as the polymer matrix wears away. In essence the wear continually refreshes the surface with newly exposed particles. Conversely, since ion transport is throughout the bulk of the polymer compositions of Konagaya, they are continually losing ions at all depths.

Thus, although both Konagaya and we seek to enhance the antimicrobial performance of polymers through the use of hydrophilic materials, we do so in different ways and attain different results. Konagaya creates a hydrophilic matrix in which the antimicrobial agent is dispersed so as to make all the dispersed agent accessible. We preserve the non-hydrophilic and other physical characteristics of the matrix resin, but employ homogeneously dispersed micro-particles of hydrophilic polymer having a high concentrations of an inorganic antimicrobial agent dispersed therein, for serving as extra-strength reservoirs of antimicrobial agent.

In closing, while the foregoing discussion speaks of the matrix phase of our composition being non-hydrophilic, it is to be noted that we also contemplate and claim embodiments wherein the matrix phase is a hydrophilic material, but one having a different degree of hydrophilicity such that the use of our novel antimicrobial particles, again as a discrete phase, enables one to tailor the rate of release of the antimicrobial agent. This concept has not been addressed by the Patent Office and, in any event, is nowhere suggested in Konagaya or any reference cited. Thus, the discussion above should not be construed as relinquishing those aspects of the present invention.

I hereby state that all statements made herein of my knowledge are true, all statements made herein on information and belief are believed to be true and all statements made herein are made with the knowledge that whoever, in any matter within the jurisdiction of the Patent and Trademark Office, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false wiring or document knowing the same to contain any false, fictitious or fraudulent statements or entry, shall be subject to the penalties set forth under 18 USC 1001, and that violations of this paragraph may jeopardize the validity or enforceability of any patent resulting therefrom.

Respectfully submitted



Jeffrey A. Trogolo, PhD
Chief Technology Officer
AgION Technologies Inc.
60 Audubon Road
Wakefield, MA 01880
781-224-7104